



**UNITED STATES DEPARTMENT OF COMMERCE
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08/594,175	01/31/96	WATKINS	D

JOHN F. VODOPIA
3 LONE OAK DR
CENTERPORT NY 11721

15M1/0529

EXAMINER
KISHORE, G

ART UNIT	PAPER NUMBER
1502	3

05/29/97

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-38 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-38 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1502

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear from the specification whether 'CATEZOMES' as recited on page 6 of the specification are liposomes made of instant lipids and whether they are available commercially. Furthermore, if a fatty acid is already linked to the amine group as recited on page 6 of the specification, it is unclear how one can react another fatty acid with this compound to obtain a salt. The way the methodology is recited is confusing. The examples given do not clarify this confusion.

2. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The full chemical name of 'A-ADDA' should be recited in the claims. Furthermore, as pointed out above, the specification indicates the addition of another fatty acid to the amide compound formed from DDA and a fatty acid. Instant claims do not recite an additional fatty acid.

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The examiner suggests careful revision of the independent claims to indicate clearly the compound which forms the bilayers. Claim 35 in particular, should recite the compound clearly.

‘Said load material’ in claims 2 and 3 and ‘said buffer’ in 3 have no antecedent basis in claim 1.

It is unclear what applicants intend to convey by ‘said buffer -----dispersing includes H₂O’ in claims 4 and 21. Buffers are made of water. ‘Includes’ is indefinite (also in claim 5-7, 9, 16, 17, 21-23, 26-27, and 33-35).

It is unclear what applicants intend to convey by ‘applying sufficient ---- specified dimension’ in claims 9 and 26. The terms sufficient and specified should be defined.

Claim 10 should recite adequately how the A-ADDA is prepared. The examiner suggests the deletion of ‘around’ in claims 10, 11, 27-28 and ‘about’ in claims 14, 31.

It is unclear what ‘claims’ in claim 12 intended to convey.

What is meant by ‘occurrence of a triggering condition in claim 35? What are these conditions?

It is unclear where the proteins are and how they readily adhere as recited in claim 36.

It is unclear what ‘controlling the salt bridge’ in claim 37 means.

The examiner suggests the deletion of ‘one of’ in claims 35 and 38 and recite the components in a Markush format.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 18-38 are rejected under 35 U.S.C. 102(b) as being anticipated by applicants' statements of prior art or EP 0 158 441.

As pointed out above, the specification on page 6 appear to indicate the commercial availability of the claimed liposomal composition. The method by which it is prepared has no significance in composition claims, in the absence of showing of patentably significant differences between the available product and the claimed product.

EP teaches liposomal composition containing instant lipid (note the abstract, and examples).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was

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made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 6. Claims 18-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carbonell(5,494,803).**

Carbonell teaches that di and trialkyl quaternary ammonium salts are routinely used in the preparation of liposomes (note column 4, line 60 et seq.). The use of instant quaternary ammonium compounds therefore, in the absence of showing unexpected results, would have been prima facie obvious to one of ordinary skill in the art.

- 7. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over JA 008 2311 in view of cited above.**

JA teaches a process of preparation of liposomes using phospholipids; the process involves dispersing the lipid in an aqueous medium and subjecting the medium to high shear (note the abstract). Although JA teaches the use of other synthetic lipids, it does not specifically teach the use of instant compounds.

Carbonell as pointed out above teaches that the use of di and trialkyl quaternary ammonium salts in liposomal preparations is routinely practiced in the art. The use of these salts in the teachings of JA, with the expectation of obtaining similar results, would have been prima facie obvious to one of ordinary skill in the art.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-2351.



Gollamudi S. Kishore, PhD
Primary Examiner
Group 1500

gsk

May 24, 1997